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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,980	11/27/2001	John E. Carlson	2748 CON	2946

7590 06/07/2005

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150 Glover Avenue  
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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
	3731

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/994,980	CARLSON ET AL.
	Examiner	Art Unit
	Michael Thaler	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 March 2005.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 16-19,22-33 and 36-44 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 16-19,22-33 and 36-44 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Feb. 15, 2005 has been entered.

Claims 1-15 and 45-50 should be listed as "Canceled" instead of "Withdrawn" since they were canceled in the response filed March 19, 2004.

The amendment filed August 18, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the new material at the end of the paragraph beginning at page 6, line 14 of the specification as well as the new material in figure 1 of the drawings. Applicant is required to cancel the new matter in the reply to this Office Action.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the locking structure defined in claims

23 and 37 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 1, there is no antecedent basis for "the braid".

Claims 16-19 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. (5,201,756) in view of Makower et al. (5,380,290). Horzewski et al. disclose the steps of positioning a radially expandable sleeve (e.g. 90 in figures 5A and 5B) over a guidewire and inserting into the radially expandable sleeve a dilator 160. (figure 6C) to expand the sleeve (col. 13, lines 9-13). Horzewski et al. fail to disclose the step of forming a percutaneous tissue tract to the target vessel. However, Makower et al. teach that such a tissue tract should be formed (by needle 14) prior to the introduction of a guidewire therethrough apparently in order to obtain the advantage of facilitating the introduction of the guidewire. It

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would have been obvious to form a percutaneous tissue tract to the target vessel in the Horzewski et al. procedure so that it too would have this advantage. As to claim 19, the radially expandable sleeve in the embodiment of figures 1A to 2F has an elastic structure so that its cross-section will collapse after expansion. As to claims 26-29, Horzewski et al. fail to disclose the claimed dimensions. However, it would have been obvious to so dimension the Horzewski et al. as claimed in order to fit within a blood vessel.

Claims 30-33 and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. (5,201,756) in view of Makower et al. (5,380,290) as applied to claims 16-19 and 22-29 above, and further in view of Dubrul et al. (5,431,676). Horzewski et al. fail to disclose the expandable sleeve comprising a tubular braid. However, it is old and well known in this art to construct expandable sleeves as tubular braids so that they expand smoothly. For example, Dubrul et al. teach that an expandable sleeve should be constructed as a tubular braid for this reason (col. 6, lines 40-61, col. 11, lines 25-29 and col. 12, lines 7-10) It would have been obvious to so construct the Horzewski et al. expandable sleeve so that it too would have this advantage. The expandable sleeve constructed as a tubular braid would retain its larger diameter after the

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dilator is removed when the outer layer is plastically deformable as indicated in col. 6, line 46-48 of Dubrul et al. Alternatively, the expandable sleeve constructed as a tubular braid would retain its larger diameter after the dilator is removed when the outer tube of the dilator to remains in place as explained in the analysis regarding claim 33 as follows. As to claim 33, Horzewski et al. fail to disclose using an outer tube of the dilator to remain in place after the dilator is removed to maintain the large diameter of the sleeve. However, it is old and well known in this art to so construct dilators (as admitted by applicant on page 5, lines 32-33) so that the main portion of the dilator can be removed leaving the outer tube or sheath in place. It would have been obvious to so construct the Horzewski et al. dilator so that it too would have this advantage.

Applicant's arguments filed Jan. 24, 2005 have been fully considered but they are not persuasive. As to the new matter objection, although the original specification and originally filed claims 23 and 37 refer broadly to a locking structure, they do not disclose the details of the locking structure (e.g. the tether 15 extending axially through sleeve 12) found in the amendment to the specification and figure 1 of the drawings. Contrary to applicant's remarks, Horzewski et al. disclose the

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steps of positioning a radially expandable sleeve 90 over a guidewire and inserting into the radially expandable sleeve a dilator 160 to expand the expansible sleeve to provide an access lumen to the blood vessel. After dilator 150 is withdrawn, as described in col. 13, lines 3-5, the guidewire remains in the patient. Then, when dilator 160 is inserted into the sleeve 90 and thus into the patient, as described in col. 13, lines 9-13, it is clearly inserted over the guidewire. Note also that dilator 160 has a central lumen to accept the guidewire.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.



mht  
6/2/05

MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731